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27572 7590 12/02/2009

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER

ZHENG, LI

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/02/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,720

12/22/2005

Richard F. Allison

6550-000072/NPB

9816

TITLE OF INVENTION: EXPRESSION OF A RECOMBINANT TRANSGENE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	03/02/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27572 7590 12/02/2009

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,720	12/22/2005	Richard F. Allison	6550-000072/NPB	9816

TITLE OF INVENTION: EXPRESSION OF A RECOMBINANT TRANSGENE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	03/02/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ZHENG, LI	1638	800-278000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,720	12/22/2005	Richard F. Allison	6550-000072/NPB	9816
27572	7590	12/02/2009	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			ZHENG, LI	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 12/02/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 280 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 280 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/561,720	ALLISON, RICHARD F.	
	Examiner	Art Unit	
	LI ZHENG	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/31/09.
2. ☒ The allowed claim(s) is/are 236,238-251,258-291,307 and 308.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with David Suter on 11/19/09.

The claims have been amended as follows:

236. (currently amended) A method of producing a heterologous polypeptide, the method comprising:

a) providing a transgenic plant or a transgenic plant cell comprising a recombinant DNA molecule, ~~the recombinant DNA molecule comprising a promoter operably linked to a DNA sequence~~ comprising, in the 5' to 3' direction,

- i) a plant promoter;
- ii) a sequence complementary to a coding sequence for a heterologous polypeptide;
- iii) a sequence complementary to a plant virus internal ribosome entry site; and
- iv) a 3' UTR sequence having a sequence encoding a viral RNA replication initiation site;

b) growing the transgenic plant or transgenic plant cell;

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c) producing an RNA transcript of the DNA sequence in the transgenic plant or the transgenic plant cell, the RNA transcript being a complementary RNA copy of the DNA sequence;

d) infecting the transgenic plant or the transgenic plant cell with an RNA nucleic acid encoding an RNA-dependent RNA polymerase operable to recognize the viral RNA replication initiation site and convert the RNA transcript produced by the transgenic plant or the transgenic plant cell to a translatable mRNA, the mRNA having a RNA sequence comprising, in the 5' to 3' direction:

i) a sequence complementary to the 3' UTR sequence;

ii) a coding sequence of the plant virus internal ribosome entry site; and

iii) a coding sequence of the heterologous polypeptide; and

e) translating the translatable mRNA in the transgenic plant or the transgenic plant cell to form the heterologous polypeptide.

237. cancelled

238. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the plant promoter is selected from the group consisting of a constitutive promoter and an inducible promoter.

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239. (previously presented) The method of producing a heterologous polypeptide of claim 238, wherein the constitutive promoter is a cauliflower mosaic virus 35S promoter.

240. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the coding sequence for the heterologous polypeptide encodes a polypeptide selected from the group consisting of a hormone, an enzyme, a cell toxin, a viral polypeptide, a cell surface polypeptide, and an intracellular polypeptide.

241. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the internal ribosome entry site is selected from the group consisting of a turnip mosaic potyvirus IRES, a tobamovirus IRES, and a hibiscus chlorotic ringspot virus IRES.

242. The method of producing a heterologous polypeptide of claim 236, wherein the sequence complementary to an internal ribosome entry site is a sequence complementary to a picornavirus internal ribosome entry site.

243. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the 3' UTR sequence is obtained from a positive strand single-stranded RNA plant virus RNA with no DNA stage.

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244. (previously presented) The method of producing a heterologous polypeptide of claim 236, further comprising a sequence complementary to an intron.

245. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein said DNA sequence further comprises a transcription termination signal sequence.

246. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the transgenic plant is a dicotyledonous plant.

247. (previously presented) The method of producing a heterologous polypeptide of claim 246, wherein the dicotyledonous plant is a *Nicotiana* plant.

248. (previously presented) The method of producing a heterologous polypeptide of claim 247, wherein the *Nicotiana* plant is a *Nicotiana benthamiana* plant.

249. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the infecting the transgenic plant or the transgenic plant cell for synthesis of an RNA complementary to an RNA transcript of the recombinant DNA comprises infecting the transgenic plant or the transgenic plant cell with a positive strand single-stranded RNA plant virus operable to recognize the viral RNA replication

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initiation site and convert the RNA transcript produced by the transgenic plant or the transgenic plant cell to a translatable mRNA.

250. (previously presented) The method of producing a heterologous polypeptide of claim 249, wherein the positive strand single-stranded RNA plant virus is a positive strand single-stranded RNA plant virus having no DNA stage.

251. (previously presented) The method of producing a heterologous polypeptide of claim 250, wherein the positive strand single-stranded RNA plant virus having no DNA stage is selected from the group consisting of a Bromovirus, a Tobacco etch virus, a Tobacco vein mottle virus, and a Pepper mottle virus.

252-256. cancelled

257. cancelled

258. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein the heterologous polypeptide produced in a cell infected with the RNA nucleic acid when compared as a molar ratio to the amount of the heterologous polypeptide produced in a cell not provided the RNA nucleic acid, ranges at least from about 50:1 to about 10,000:1.

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259. The method of producing a heterologous polypeptide of claim 236, wherein said method of producing a heterologous polypeptide in a transgenic plant is used to confer disease resistance to a transgenic plant further comprising conferring resistance to subsequent infection from a second positive strand single-stranded RNA virus.

260. (currently amended) A recombinant DNA molecule comprising ~~a promoter operably linked to a DNA sequence comprising~~, in the 5' to 3' direction:

- a) a plant promoter;
 - b) a sequence complementary to a coding sequence for a heterologous polypeptide;
 - c) a sequence complementary to a plant internal ribosome entry site;
- and
- d) a 3' UTR sequence comprising a DNA sequence of a 3'UTR RNA sequence of a positive strand single-stranded RNA plant virus.

261. (previously presented) The recombinant DNA molecule of claim 260, wherein the plant promoter is selected from the group consisting of a constitutive promoter and an inducible promoter.

262. (previously presented) The recombinant DNA molecule of claim 261, wherein the constitutive promoter is a cauliflower mosaic virus 35S promoter.

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263. (previously presented) The recombinant DNA molecule of claim 260, wherein the coding sequence for the heterologous polypeptide encodes a polypeptide selected from the group consisting of a hormone, an enzyme, a cell toxin, a viral polypeptide, a cell surface polypeptide, and an intracellular polypeptide.

264. (previously presented) The recombinant DNA molecule of claim 260, wherein the sequence complementary to a plant internal ribosome entry site is a sequence complementary to a plant internal ribosome entry site (IRES) selected from the group consisting of a turnip mosaic potyvirus IRES, a tobamovirus IRES, and a hibiscus chlorotic ringspot virus IRES.

265. (previously presented) The recombinant DNA molecule of claim 260, wherein the sequence complementary to a plant internal ribosome entry site is a sequence complementary to a tobamovirus internal ribosome entry site.

266. (previously presented) The recombinant DNA molecule of claim 260, wherein the 3' UTR DNA sequence is a DNA copy of a positive strand single-stranded RNA plant virus RNA having no DNA stage.

267. (previously presented) The recombinant DNA molecule of claim 266, wherein the positive strand single-stranded RNA virus RNA having no DNA stage is a 3' UTR of a bromovirus.

268. (previously presented) The recombinant DNA molecule of claim 260, further comprising a sequence complementary to an intron.

269. (previously presented) The recombinant DNA molecule of claim 260, further comprising a transcription termination signal.

270. (previously presented) A transgenic plant comprising the recombinant DNA molecule of claim 260.

271. (previously presented) A transgenic plant cell of claim 270.

272. (previously presented) The transgenic plant of claim 270, wherein the transgenic plant is a transgenic dicotyledonous plant.

273. (previously presented) The transgenic dicotyledonous plant of claim 272, wherein the transgenic dicotyledonous plant is a transgenic *Nicotiana* plant.

274. (previously presented) Transgenic seed comprising the recombinant DNA molecule of claim 260.

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275. (currently amended) A vector having at least one site for insertion of a recombinant DNA construct having inserted therein the recombinant DNA molecule ~~for expressing a heterologous polypeptide in a transgenic cell of claim 260 comprising coding sequence of a heterologous polypeptide in an antisense orientation.~~

276. (currently amended) A vector according to claim 275, wherein the at least one site for insertion further ~~of a sequence comprising coding sequence of a heterologous polypeptide in an antisense orientation~~ comprises a recombination site.

277. (currently amended) A vector according to claim 276 ~~275~~, wherein the recombination site is selected from the group consisting of a bacteriophage lambda *att* site and a topoisomerase I-based recombination site.

278. (currently amended) A vector according to claim 275, wherein the at least one site for insertion further ~~of a sequence comprising coding sequence of a heterologous polypeptide in an antisense orientation~~ comprises at least one restriction enzyme recognition site.

279. (currently amended) A vector according to claim 278 ~~275~~, wherein the at least one restriction enzyme recognition site comprises a polylinker.

280. A recombinant RNA molecule comprising, in the 5' to 3' direction:

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- a) an RNA sequence comprising a sequence complementary to a coding sequence for a heterologous polypeptide;
- b) a sequence complementary to an internal ribosome entry site; and
- c) a 3' UTR of a positive strand single-stranded RNA virus.

281. The recombinant RNA molecule of claim 280, wherein the coding sequence for a heterologous polypeptide encodes a polypeptide selected from the group consisting of a hormone, an enzyme, a cell toxin, a viral polypeptide, a cell surface polypeptide, and an intracellular polypeptide.

282. The recombinant RNA molecule of claim 280, wherein the sequence complementary to an internal ribosome entry site is a sequence complementary to an IRES selected from the group consisting of a picornavirus IRES, a foot-and-mouth disease virus IRES, an encephalomyocarditis virus IRES, a hepatitis A virus IRES, a hepatitis C virus IRES, a human rhinovirus IRES, a poliovirus IRES, a swine vesicular disease virus IRES, a turnip mosaic potyvirus IRES, a human fibroblast growth factor 2 mRNA IRES, a pestivirus IRES, a Leishmania RNA virus IRES, a Moloney murine leukemia virus IRES, a human rhinovirus 14 IRES, an aphthovirus IRES, a human immunoglobulin heavy chain binding protein mRNA IRES, a *Drosophila* Antennapedia mRNA IRES, a human fibroblast growth factor 2 mRNA IRES, a hepatitis G virus IRES, a tobamovirus IRES, a vascular endothelial growth factor mRNA IRES, a Coxsackie B group virus IRES, a c-myc protooncogene mRNA IRES, a human MYT2 mRNA IRES, a

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human parechovirus type 1 virus IRES, a human parechovirus type 2 virus IRES, a eukaryotic initiation factor 4G1 mRNA IRES, a *Plautia stali* intestine virus IRES, a Theiler's murine encephalomyelitis virus IRES, a bovine enterovirus IRES, a connexin 43 mRNA IRES, a homeodomain protein Gtx mRNA IRES, an AML1 transcription factor mRNA IRES, an NF-kappa B repressing factor mRNA IRES, an X-linked inhibitor of apoptosis mRNA IRES, a cricket paralysis virus RNA IRES, a p58(PITSLRE) protein kinase mRNA IRES, an ornithine decarboxylase mRNA IRES, a connexin-32 mRNA IRES, a bovine viral diarrhea virus IRES, an insulin-like growth factor I receptor mRNA IRES, a human immunodeficiency virus type 1 gag gene IRES, a classical swine fever virus IRES, a Kaposi's sarcoma-associated herpes virus IRES, a short IRES selected from a library of random oligonucleotides, a Jembrana disease virus IRES, an apoptotic protease-activating factor 1 mRNA IRES, a *Rhopalosiphum padi* virus IRES, a cationic amino acid transporter mRNA IRES, a human insulin-like growth factor II leader 2 mRNA IRES, a giardiavirus IRES, a Smad5 mRNA IRES, a porcine teschovirus-1 talfan IRES, a *Drosophila* Hairless mRNA IRES, an hSNM1 mRNA IRES, a Cbfa1/Runx2 mRNA IRES, an Epstein-Barr virus IRES, a hibiscus chlorotic ringspot virus IRES, a rat pituitary vasopressin V1b receptor mRNA IRES, and a human hsp70 mRNA IRES.

283. The recombinant RNA molecule of claim 280, wherein the sequence complementary to an internal ribosome entry site is a sequence complementary to a picornavirus internal ribosome entry site.

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284. The recombinant RNA molecule of claim 280, wherein the 3' UTR of a positive strand single-stranded RNA virus is a 3' UTR of a positive strand single-stranded RNA virus having no DNA stage.

285. The recombinant RNA molecule of claim 284, wherein the 3' UTR of a positive strand single-stranded RNA virus having no DNA stage is a 3' UTR of a bromovirus.

286. The recombinant RNA molecule of claim 280, further comprising a sequence complementary to an intron.

287. A transgenic cell or transgenic plant comprising the recombinant RNA molecule of claim 280.

288. The transgenic cell of claim 287, wherein the transgenic cell is a transgenic plant cell.

289. The transgenic plant of claim 287, wherein the transgenic plant is a transgenic dicotyledonous plant.

290. The transgenic dicotyledonous plant of claim 289, wherein the transgenic dicotyledonous plant is a transgenic *Nicotiana* plant.

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291. The transgenic *Nicotiana* plant of claim 290, wherein the transgenic *Nicotiana* plant is a transgenic *Nicotiana benthamiana* plant.

292-306. cancelled

307. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein infecting the transgenic plant or the transgenic plant cell with an RNA nucleic acid comprises infecting the transgenic plant or the transgenic plant cell with a positive strand single-stranded RNA plant virus having a RNA genome operable to recognize and activate the viral RNA replication initiation site and convert the RNA transcript produced by the transgenic plant or transgenic plant cell to a translatable mRNA.

308. (previously presented) The method of producing a heterologous polypeptide of claim 236, wherein infecting the transgenic plant or the transgenic plant cell with an RNA nucleic acid comprises transfecting the transgenic plant or the transgenic plant cell with a RNA of a positive strand single-stranded virus operable to recognize and activate the viral RNA replication initiation site and convert the RNA transcript produced by the transgenic plant or transgenic plant cell to a translatable mRNA.

Status of Rejections

All the rejections are withdrawn in light of the claims amendments and this amendment.

Allowable Subject Matter

Claims 236,238-251,258-291,307 and 308 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638